6. What are the possible side effects of LOTRONEX?

Constipation is the most common side effect among women with IBS who take LOTRONEX**. Some patients have developed serious bowel side effects while taking LOTRONEX.**
Read the section "What is the most important information I should know about LOTRONEX?" at the beginning of this Medication Guide for information about the serious side effects you may get with LOTRONEX.

This Medication Guide does not tell you about all the possible side effects of LOTRONEX. Your doctor or pharmacist can give you a more complete list.

7. General information about the safe and effective use of LOTRONEX

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you have any questions or concerns about LOTRONEX, ask your doctor. Do not use LOTRONEX for a condition for which it was not prescribed. Do not share your medicine with other people. It may harm them.

Your doctor or pharmacist can give you more information about LOTRONEX that was written for healthcare professionals. You can also contact the company that makes LOTRONEX (toll free) at 1-888-825-5249 or at www.lotronex.com.

8. What are the ingredients of LOTRONEX?

Active Ingredient: alosetron hydrochloride
Inactive Ingredients: lactose (anhydrous), magnesium stearate, microcrystalline cellulose, and pregelatinized starch. The white film-coat for the 0.5-mg tablet contains hypromellose, titanium dioxide, and triacetin. The blue film-coat for the 1-mg tablet contains hypromellose, titanium dioxide, triacetin, and indigo carmine.

This Medication Guide has been approved by the US Food and Drug Administration.

(Date of Issue) MG-

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PATIENT-PHYSICIAN AGREEMENT FOR LOTRONEX

LOTRONEX® (alosetron hydrochloride) is only for women with severe irritable bowel syndrome (IBS) whose main problem is diarrhea and who did not get the relief needed from other treatments. LOTRONEX has not been shown to help men with IBS or patients under age 18.
My doctor, or a healthcare provider under a doctor's direction, answered my questions about treatment with LOTRONEX. I have read and I understand the Medication Guide for LOTRONEX, and

- I understand that some patients using LOTRONEX have had serious bowel conditions (ischemic colitis and complications of constipation). I understand that these serious conditions can happen suddenly, and that they may lead to a hospital stay, and in rare cases, blood transfusions, surgery, and death. I also understand that certain

patients may be more likely to develop a serious bowel condition while taking LOTRONEX. These include older patients, those who have other health problems and those who take other medicines that may cause constipation.

- My doctor and I agree that my IBS is severe and that other treatments have not given me the relief that I need. I also agree that I meet all of the requirements described in the section of the Medication Guide "What is the most important information I should know about LOTRONEX?" I understand that these requirements help to make sure that LOTRONEX is used only by patients who are likely to have more benefit from treatment than risk.

- I don't have any problems listed in the section of the Medication Guide "Who should not take LOTRONEX?" that prevents me from taking LOTRONEX.

- I will follow instructions in the Medication Guide about:
    - **telling my doctor**, before taking LOTRONEX, about any illnesses I have, or other medicines I am taking or planning to take.
    - **taking LOTRONEX** exactly as my doctor prescribes it.
    - **stopping LOTRONEX** and calling my doctor right away if I get constipated, if I have new or worse pain in my abdomen, or if I see blood in my bowel movements.
    - **calling my doctor** again if the constipation I called about before has not gotten better.
    - **not starting LOTRONEX again** unless my doctor tells me to do so, if I stopped taking it because I got constipated.
    - **talking with my doctor 4 weeks after starting LOTRONEX** to recheck my IBS symptoms.
    - **stopping LOTRONEX and calling my doctor** if my IBS symptoms have not improved after 4 weeks of taking 1 mg 2 times a day.

I understand that LOTRONEX should be prescribed only by doctors who have signed up with the company that makes the drug. Doctors in the program must:

- fully discuss the drug's benefits and risks with each patient.
- sign this agreement with each patient before giving the initial prescription. It is not necessary to sign an agreement more than once.
- use a special sticker on all LOTRONEX prescriptions so that pharmacists know the doctor has signed up.

If I see other doctors about my IBS or possible side effects from LOTRONEX, I will let the doctor who prescribed LOTRONEX know.

My signature below indicates I have read, understood, and agree with all the statements made above. I would like to begin treatment with LOTRONEX.

_____

Name of Patient (print)

_____ _____

Signature Date

SECTION FOR THE PHYSICIAN

I am enrolled in the Prescribing Program for LOTRONEX, and I will continue to follow the requirements of the Program.

I, or a healthcare provider under a physician's direction, have given the patient named above:

- a copy of the Medication Guide for LOTRONEX, and instructed the patient to read it carefully before signing this Agreement, and to take it home.
- counseling about the benefits and risks of LOTRONEX.
- appropriate instructions for taking LOTRONEX.
- answers to all of the patient's questions about treatment with LOTRONEX.
- a prescription for LOTRONEX that has the program sticker affixed on it to alert pharmacists I am enrolled in the Prescribing Program for LOTRONEX.

The patient signed the Patient-Physician Agreement in my presence after I counseled the patient, asked if the patient had any questions about treatment with LOTRONEX, and answered all questions to the best of my ability.

_____

Name of Physician (print)

_____ _____

Signature Date

After the patient and the physician sign this Patient-Physician Agreement, give a copy to the patient and put the original signed form in the patient's medical record.

PRESCRIBING PROGRAM FOR LOTRONEX™:

PHYSICIAN ENROLLMENT FORM

The Prescribing Program for LOTRONEX was implemented to help reduce risks of serious gastrointestinal adverse events, some fatal, associated with this medicine. The program is intended to help physicians and their patients understand the benefits and risks of treatment with LOTRONEX in order to make fully informed decisions.

I wish to participate in the Prescribing Program for LOTRONEX (PPL) and acknowledge that I have read the complete Prescribing Information for LOTRONEX and understand and will follow the requirements of the PPL described below.

- For safety reasons, LOTRONEX is approved only for women with severe, diarrhea-predominant irritable bowel syndrome (D-IBS) who have:
  - Chronic IBS symptoms (generally lasting for 6 months or longer),
  - had anatomic or biochemical abnormalities of the gastrointestinal tract excluded, and
  - not responded adequately to conventional therapy.

  Diarrhea-predominant IBS is severe if it includes diarrhea and one or more of the following: